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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,009	11/08/1999	CAROL MORRIS	047763-5010	3768

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/02/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/367,009

Applicant(s)

MORRIS ET AL.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Applicant cancels claims 1, 3, 6-12 and adds new claims 15-29.

Claims 15-29 however are numbered as 13-27, according to rule 126.

Accordingly, claims 13-27 are examined in the instant application.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

New claims 16-20 are rejected under 35 USC 112, first paragraph, pertaining to lack of a clear written description, for reasons already of record in paper No:17.

Applicant argues that the new claims are drawn to a small subgenus of proteins with the recited physical properties, and one could readily identify any of the proteins, using methods known in the art.

Concerning SEQ ID NO:3, Applicant asserts that the Office stated that the specification provides adequate written description or a method for screening cancer, comprising detecting the a tear sample the presence of the amino acid sequence consisting of SEQ ID NO:3. Applicant asserts that SEQ ID NO:3 was never isolated, rather the full length was isolated and only its N-terminus was sequenced to reveal the amino acid sequence of SEQ ID NO:3. Applicant asserts that it is not possible for a protein with a sequence "consisting" of SEQ ID NO:3 to have a molecular weight of about 10 kD.

Applicant's arguments in paper No:18 have been considered but are found not to be persuasive for the following reasons:

Claims 16-20 encompass a method for detecting cancer, comprising detecting in a tear sample, the presence of a protein having a molecular weight of about 10 kD, and a pI of about 5.1, wherein the protein is detected by a labeled probe which binds to any part of the protein, or any part of the N-terminus of the protein, or antibody that specifically binds to the protein at a part of the protein that is not SEQ ID NO:3.

It is noted that except for a fragment of SEQ ID NO:3, the structure of the whole protein is not disclosed. It is further noted that it is not known whether SEQ ID NO:3 is exposed on the surface of the claimed protein such that an antibody or a labeled probe can bind to the claimed protein via SEQ ID NO:3.

Thus the claims do not meet the written description requirement because there is no disclosure of the structure of the part of the claimed protein where a labeled probe or the antibody binds to.

In addition, concerning SEQ ID NO:3, it is noted that the Examiner stated in previous Office action that the "N-terminal sequence" of a protein having a molecular weight of 10 kD and a pI of 5.1 consists of SEQ ID NO:3. The Examiner did not state that the whole protein having a molecular weight of 10 kD and a pI of 5.1 consists of SEQ ID NO:3.

Further, although SEQ ID NO:3 is not isolated, SEQ ID NO:3 is part of the claimed whole protein having a molecular weight of 10 kD and a pI of 5.1, and detection of SEQ ID NO:3 would detect the claimed protein having a molecular weight of 10 kD and a pI of 5.1.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

New claims 16-20 are rejected under 35 USC 112, first paragraph, pertaining to lack of enablement for a method for screening cancer, comprising detecting in a tear sample, the presence of a protein having a molecular weight of about 10 kD, and a pI pf about 5.1, "wherein the protein is detected by a labeled probe which binds to any part of the protein, or any part of the N-terminus of the protein", or by "an antibody that specifically binds to the protein" for reasons already of record in paper No:17.

Applicant argues that it is not necessary for an antibody to specifically or selectively binds to a protein having a molecular weight of about 10 kD, and a pI pf about 5.1 in order to detect the presence of the claimed protein, because the physical properties of the protein would be sufficient to identify its presence.

Applicant's arguments in paper No:18 have been considered but are found not to be persuasive for the following reasons:

Claims 16-20 encompass a method for detecting cancer, comprising detecting in a tear sample, the presence of a protein having a molecular weight of about 10 kD, and a pI pf about 5.1, wherein the protein is detected by a labeled probe which binds to any part of the protein, or any part of the N-terminus of the protein that comprises SEQ ID NO:3.

It is noted that except for a fragment of SEQ ID NO:3, the structure of the whole protein is not disclosed. It is further noted that it is not known whether SEQ ID NO:3 is exposed on the surface of the claimed protein such that an antibody or a labeled probe can bind to the claimed protein via SEQ ID NO:3.

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Thus without the structural information of the part of the protein other than SEQ ID NO:3, where a label or an antibody binds to, one would not know how to make the label or the antibody for use in the claimed method. Further, one would not know how to use the antibody that binds to SEQ ID NO:3, because it is unpredictable that said antibody could bind to the claimed protein via SEQ ID NO:3.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE, NEW REJECTION.

Claims 13-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting cancer, comprising detecting in a tear sample, the presence of a protein having a molecular weight of 10 kD, and a pI of 5.1, wherein the protein is detected by two-dimensional gel electrophoresis, does not reasonably provide enablement for a method for detecting cancer, comprising detecting in a tear sample, the presence of a protein having a molecular weight of about 10 kD, and a pI of about 5.1, wherein the protein is detected by electrophoresis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 13-14 are drawn to a method for detecting cancer, comprising detecting in a tear sample, the presence of a protein having a molecular weight of about 10 kD, and a pI pf about 5.1, wherein the protein is detected by electrophoresis.

It is noted that electrophoresis encompasses one-dimensional electrophoresis.

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The specification, the response and the COBON Declaration of 03/14/02 of disclose that the detection of breast, lung, colon and prostate cancer is done by detecting the frequency of expression of a spot on 2D-PAGE of a tear sample, wherein said spot has a MW of 10 KD and a pl of 5.1, and wherein cancer patients have higher frequency of the presence of said spot in a tear sample (table 2 on page 7 of the specification, and the annexed table C in the Declaration). The specification also discloses that partial sequencing of the protein isolated from said spot show a sequence of SEQ ID NO:3 (p.7 of the specification).

One cannot extrapolate the teaching of the specification to the scope of the claims. It is not clear how one could practice the claimed invention, because detecting the presence of the claimed protein in one-dimensional electrophoresis could be easily masked by the presence of unrelated proteins having similar molecular weight, but different pl.

REJECTION UNDER 35 USC 102

New claims 13-15, 21-27 are rejected under 35 USC 102(a) pertaining to anticipation by Molloy et al remains for reasons already of record in paper No.17.

Applicant requests that the rejection be held in abeyance, until such time that the certified copy of the prior application, which is the Australian application PO 5009, is submitted.

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Rejection remains. The rejection however is hold in abeyance, until such time that the certified copy of the prior application, which is the Australian application PO 5009, is submitted.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

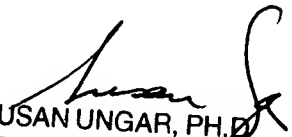
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872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

June 30, 2003


SUSAN UNGAR, PH.D.
PRIMARY EXAMINER